APPENDIX B
TO DEFENDANTS' TRIAL BRIEF

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION MDL No. 2327

THIS DOCUMENT RELATES TO:

Cases Identified in the Exhibit
Attached Hereto

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Jerry Blaivas, M.D.)

Pending before the court is the Motion to Exclude Certain General Opinions of Jerry Blaivas, M.D. [ECF No. 2038] filed by defendants Johnson & Johnson and Ethicon, Inc. (collectively "Ethicon"). The Motion is now ripe for consideration because briefing is complete.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 75,000 cases currently pending, approximately 30,000 of which are in this MDL.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict*

Litigation in Products Liability Cases 3 (2011). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure. In Pretrial Order ("PTO") No. 217, the court instructed the parties to file only one *Daubert* motion per challenged expert, to file each motion in the main MDL—as opposed to the individual member cases—and to identify which cases would be affected by the motion. PTO No. 217, at 4.[1]

II. Preliminary Matters

Before plunging into the heart of the Motion, a few preliminary matters need to be addressed.

I am compelled to comment on the parties' misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of expert testimony based on its reliability and relevance. In other words, the parties have comparatively examined expert testimony and have largely overlooked *Daubert*'s core considerations for assessing expert

[1] Ethicon identified the Wave 1 cases affected by this Motion in its attached Exhibit A [ECF No. 2038-1], which the court has attached to this Memorandum Opinion and Order. At the time of transfer or remand, the parties will be required to designate relevant pleadings from MDL 2327, including the motion, supporting memorandum, response, reply, and exhibits referenced herein.

testimony. Although I recognize the tendency of my prior evidentiary determinations to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are misplaced, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper for the admission of expert testimony, as well as my duty to "respect[ ] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert testimony and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular expert testimony and objections currently before me, I assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the expert testimony contained therein.

Finally, I have attempted to resolve all possible disputes before transfer or remand, including those related to the admissibility of expert testimony pursuant to *Daubert*. Nevertheless, in some instances I face *Daubert* challenges where my interest in accuracy counsels reserving ruling until the reliability of the expert

testimony may be evaluated at trial. At trial, the expert testimony will be tested by precise questions asked and answered. The alternative of live *Daubert* hearings is impossible before transfer or remand because of the numerosity of such motions in these seven related MDLs. As these MDLs have grown and the expert testimony has multiplied, I have become convinced that the critical gatekeeping function permitting or denying expert testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert testimony offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of "junk science" looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalizations of expert testimony, and incomplete deposition transcripts. This, combined with the above-described practice of recycling expert testimony, objections, and the court's prior rulings, creates the perfect storm of obfuscation. Where further clarity is necessary, I believe it can only be achieved through live witness testimony—not briefing—I will therefore reserve ruling until expert testimony can be evaluated firsthand.

III. Legal Standard

By now, the parties should be intimately familiar with Rule 702 of the Federal Rules of Evidence and *Daubert*, so the court will not linger for long on these

standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

> (1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts "principles and methodology" above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g.*, *Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

IV. Discussion

Dr. Blavais is a urologist with extensive experience treating patients with complications related to mesh sling surgery.

a. Alternative Design and Products

First, Ethicon argues that Dr. Blaivas should not be permitted to testify that alternative procedures are safer than Ethicon's mesh products. Expert testimony on this subject, Ethicon claims, is not relevant. The relevance of this expert testimony is better decided on a case-by-case basis. Accordingly, I **RESERVE** ruling on this matter until trial.

Ethicon also objects to the reliability of Dr. Blaivas's expert testimony about whether alternative procedures are safer than Ethicon's mesh products. In my view, the reliability of this expert testimony is heavily dependent on Dr. Blaivas's clinical experiences.[2]

In the abstract, experience—on its own or accompanied by little else—is a reliable basis for expert testimony. *See Kumho*, 526 U.S. at 156. But the reliability inquiry must probe into the relationship between the experience and the expert testimony:

> If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts.

Fed. R. Evid. 702 advisory committee's note to 2000 amendment. Here, the court does not have enough information to judge the reliability or relevance of Dr. Blaivas's particular experience.

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[2] This is especially so because, while Dr. Blaivas reviewed medical literature, he has characterized the medical literature concerning the safety of mesh devices as "poor."

In this specific context, I am without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony based primarily on an expert's clinical experiences. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

Second, Ethicon claims Dr. Blaivas is not qualified to offer expert testimony about alternative designs (e.g., mesh with larger pore size or less weight). I do not need to opine on his qualifications because this aspect of his testimony is clearly unreliable. In an effort to show this expert testimony is reliable, the plaintiffs offered up an article entitled *Safety Considerations for Synthetic Sling Surgery*, which Dr. Blaivas co-authored, and noted Dr. Blaivas's reliance on the sources cited. But those sources concern hernia repair mesh and were insufficient to allow, as the authors put it, "any meaningful conclusions." Resp. Ex. 2, at 12 [ECF No. 2176-2]. Yet Dr. Blaivas never explains how this uncertainty expressed in a 2015 article—which contradicts the expert testimony he intends to offer—has been dispelled. Nor does Dr. Blaivas explain the import of the medical literature he cites to support his expert testimony. Upon review of the record, I am not satisfied that Dr. Blaivas's opinion is reliable. Ethicon's Motion is **GRANTED** on this point.

Third, Ethicon challenges the reliability of Dr. Blaivas's expert testimony about mechanical-cut and laser-cut mesh. In his report, Dr. Blaivas cites to internal Ethicon documents to support this opinion, which offer some support. But like the testimony above, the lynchpin of Dr. Elliott's testimony seems to be his experience. And as noted above, I am without information sufficient to assess whether this is a

reliable foundation. So I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

Fourth, Ethicon challenges the reliability of Dr. Blaivas's expert testimony about the implantation approach and that an alternative implantation approach would be safer. The plaintiffs focus on what they perceive as the shortcomings in Ethicon's argument, and they fail to explain why this expert testimony is reliable. Given no reason to find this expert testimony reliable, Ethicon's Motion is **GRANTED** on this point.

Fifth, Ethicon challenges the reliability of Dr. Blaivas's expert testimony about the size of the surgical trocars and the implantation technique. Neither article cited in support of this expert testimony by Dr. Blaivas supports this position, and Dr. Blaivas does not explain why these articles support his position. The same is true for the article referenced by the plaintiffs in response to Ethicon's argument—an article cited in connection with a different proposition in Dr. Blaivas's report. Accordingly, Ethicon's Motion is **GRANTED** on this point.

Sixth, Ethicon challenges the reliability of Dr. Blaivas's expert testimony about mesh length. The plaintiffs do not present any argument discussing why it is admissible (i.e., reliable). I will not make arguments for the plaintiffs; therefore, Ethicon's Motion is **GRANTED** on this point.

b. Warnings

Ethicon claims Dr. Blaivas is not qualified to offer expert testimony about product warnings, which includes expert testimony about the adequacy of the

relevant Instructions for Use ("IFU"). According to Ethicon, Dr. Blaivas is not an expert in the development of warning labels and thus is not qualified to offer expert testimony about warnings. Dr. Blaivas is not an expert in the development of warning labels. While an expert who is a urologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU. *Wise v. C. R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 521202, at *14 (S.D. W. Va. Feb. 7, 2015). Dr. Blaivas does not possess the additional expertise to offer expert testimony about what an IFU should or should not include. Accordingly, Dr. Blaivas's expert testimony about these matters is **EXCLUDED**.

c. Safety and Efficacy

Ethicon challenges the reliability of Dr. Blaivas's expert testimony about safety and efficacy and complication rates by pointing out numerous perceived flaws in the foundation of Dr. Blaivas's expert testimony. Two primary problems render this expert testimony unreliable. First, Dr. Blaivas continues to rely quite heavily on complications rates this court has excluded time and again. *E.g.*, *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 721 (S.D. W. Va. 2014). In *Huskey*, I excluded this expert testimony because "Dr. Blaivas did not explain his methodology and admitted that it was impossible to calculate an accurate complication rate." *Id.* He has not remedied these shortcomings. Second, Dr. Blaivas does not provide a reasonable explanation for his disagreement with guidelines that he helped author and that conclude mesh

products are suitable surgical options. *See, e.g.*, *Bethune v. Bos. Sci. Corp.*, No. 2:13-cv-6199, 2016 WL 2983697, at *4 (S.D. W. Va. May 20, 2016) (noting an expert's methodology "may be flawed if he does not provide an adequate explanation for why he disagrees with [contrary] studies"). Accordingly, the expert testimony is **EXCLUDED**.

d. Properties

Ethicon asks the court to exclude Dr. Blaivas's biomaterials opinions related to mesh degradation, shrinkage, and other deformations because Dr. Blaivas is unqualified and his opinions are unreliable. The plaintiffs make no response to the specific reliability challenge and I decline to raise counterarguments on their behalf. Ethicon's Motion on this matter is **GRANTED** and Dr. Blaivas's opinions on biomaterials are **EXCLUDED**. I thus find it unnecessary to address his qualifications.

e. Complications

Ethicon seeks to exclude Dr. Blaivas's testimony regarding cancer and death complications that no plaintiff in these cases has suffered. Evidence of complications that a plaintiff did not experience is irrelevant and lacking in probative value. Accordingly, to the extent that Dr. Blaivas seeks to opine on complications that no plaintiff in this wave of cases has suffered, such testimony is **EXCLUDED**.

Ethicon also challenges Dr. Blaivas's use of the terms "chronic mesh pain syndrome," "mesh cripples," and "Meshology" because these terms are inflammatory and prejudicial. The plaintiffs have sufficiently demonstrated that the term "chronic mesh pain syndrome" is used in scientific literature, as Dr. Blaivas cites to a chapter

entitled "Pain Complications of Mesh Surgery" in the academic textbook *Complications of Female Incontinence and Pelvic Reconstructive Surgery*. Ethicon's Motion regarding Dr. Blaivas's use of the term "chronic mesh pain syndrome" is **DENIED**. I agree that terms such as "mesh cripples" and "Meshology" are inflammatory and unduly prejudicial, and their use in testimony is **EXCLUDED**.

f. Product Testing

Ethicon claims Dr. Blaivas is not qualified to offer opinions about product testing Ethicon should have conducted and about what such testing would have revealed. As I have found before, "[t]here is no indication in the record that Dr. Blaivas has any experience or knowledge on the appropriate testing a medical device manufacturer should undertake." *Huskey*, 29 F. Supp. 3d at 723. Because Dr. Blaivas is not qualified to offer expert testimony of this sort, his expert testimony on this matter is **EXCLUDED**.

g. Industry Bias and Collusion

In his reports, Dr. Blaivas criticizes the medical literature about mesh products, claiming some studies are biased. If Ethicon seeks to challenge Dr. Blaivas's allegations of bias as to these studies, it may do so on cross-examination. *See Tyree*, 54 F. Supp. 3d at 559. To the extent Ethicon seeks to exclude these matters, its Motion is **DENIED**.

Dr. Blaivas also offers his opinion that Ethicon colluded with other manufacturers to influence reimbursement. Ethicon asks the court to exclude this opinion. The plaintiffs do not offer any response. Accordingly, Ethicon's Motion is

GRATNED as to this matter.

V. Recurring Issues

Many of the *Daubert* motions filed in this MDL raise the same or similar objections.

One particular issue has been a staple in this litigation, so I find it best to discuss it in connection with every expert. A number of the *Daubert* motions seek to exclude FDA testimony and other regulatory or industry standards testimony. To the extent this Motion raises these issues it is **GRANTED in part** and **RESERVED in part** as described below.

I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs, and will continue to do so in these cases, a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913, 921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible prejudicial impact under Rule 403). Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See In re C. R. Bard,* 81 F.3d at 920 ("[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value."). Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors "to erroneously conclude that regulatory compliance proved safety." *Id.* at 922. Accordingly, expert testimony related to the section 510(k) process, including subsequent enforcement

actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, is **EXCLUDED**. For the same reasons, opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations are **EXCLUDED**. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue in these cases and runs the risk of misleading the jury and confusing the issues. Insofar as this Motion challenges the FDA-related testimony discussed here, the Motion is **GRANTED**.

A number of experts also seek to opine on Ethicon's compliance with design control and risk management standards. Some of this testimony involves the FDA's quality systems regulations, and some—likely in an attempt to sidestep my anticipated prohibition on FDA testimony—involve foreign regulations and international standards. I find all of this proposed testimony of dubious relevance. Although these standards relate to how a manufacturer should structure and document risk assessment, the standards do not appear to mandate any particular design feature or prescribe the actual balance that must be struck in weighing a product's risk and utility. Nor is it clear that the European and other international standards discussed had any bearing on the U.S. medical device industry when the device in question was being designed.

Nevertheless, because the nuances of products liability law vary by state, I will refrain from issuing a blanket exclusion on design process and control standards testimony, whether rooted in the FDA or otherwise. Each standard must be assessed

for its applicability to the safety questions at issue in this litigation, consistent with state law. I am without sufficient information to make these findings at this time. Accordingly, I **RESERVE** ruling on such matters until a hearing, where the trial judge will have additional context to carefully evaluate the relevance and potential prejudicial impact of specific testimony.

Similarly, I doubt the relevance of testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by the above discussion. Again, such matters seem to say very little about the state of the product itself (i.e., whether or not it was defective) when it went on the market. But because the scope of relevant testimony may vary according to differences in state products liability law, I **RESERVE** ruling on such matters until they may be evaluated in proper context at a hearing before the trial court before or at trial.

Additional—and more broad—matters also warrant mention. While some of these concerns may not apply to this particular expert, these concerns are raised so frequently that they are worth discussing here.

First, many of the motions seek to exclude state-of-mind and legal-conclusion expert testimony. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury's fact-finding function by allowing testimony of this type, and I do the same here. *E.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g.*, *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion

by applying law to the facts is generally inadmissible."); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) ("Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony."). Additionally, an expert may not offer expert testimony using "legal terms of art," such as "defective," "unreasonably dangerous," or "proximate cause." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

Second, and on a related note, many of the motions seek to prohibit an expert from parroting facts found in corporate documents and the like. I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his or her expert opinions—assuming the expert opinions are otherwise admissible—he or she may not offer testimony that is solely a conduit for corporate information.

Third, many of the motions also ask the court to require an expert to offer testimony consistent with that expert's deposition or report or the like. The court will not force an expert to testify one way or another. To the extent an expert offers inconsistent testimony, the matter is more appropriately handled via cross-examination or impeachment as appropriate and as provided by the Federal Rules of Evidence.

Fourth, in these *Daubert* motions, the parties have addressed tertiary evidentiary matters like whether certain statements should be excluded as hearsay. The court will not exclude an expert simply because a statement he or she discussed

may constitute hearsay. *Cf. Daubert*, 509 U.S. at 595. Hearsay objections are more appropriately raised at trial.

Finally, in some of the *Daubert* motions, without identifying the specific expert testimony to be exclude, the parties ask the court to prevent experts from offering other expert testimony that the moving party claims the expert is not qualified to offer. I will not make speculative or advisory rulings. I decline to exclude testimony where the party seeking exclusion does not provide specific content or context.

VI. Conclusion

The court **DENIES in part**, **GRANTS in part**, and **RESERVES in part** the Motion to Exclude Certain General Opinions of Jerry Blaivas, M.D. [ECF No. 2038].

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 1 cases identified in the Exhibit attached hereto.

ENTER: August 26, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 1 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

EXHIBIT A TO MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF JERRY G. BLAIVAS, M.D.

ALL CASES PERTINENT TO MOTION

1. *Joan Adams v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01203 (Prolift);
2. *Marty Babcock v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01052 (TVT);
3. *Daphne Barker, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00899 (TVT);
4. *Dorothy Baugher v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01053 (TVT-O);
5. *Melissa Clayton, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00489 (Prolift);
6. *Constance Daino, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01145 (TVT);
7. *Lois Durham, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00760 (Prolift & TVT-O);
8. *Monica Freitas, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01146 (TVT);
9. *Beth Harter, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00737 (Prosima & TVT-O);
10. *Jeanie Holmes v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01206 (TVT-O);
11. *Mary Holzerland, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00875 (TVT-Secur);
12. *Myndal Johnson v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00498 (TVT);
13. *Holly Jones, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00443 (TVT);

14. *Deborah Lynn Joplin v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00787 (TVT-O);

15. *Beverly Kivel v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00591 (Gynemesh PS);

16. *Paula Kriz, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00938 (Gynemesh PS & TVT-O);

17. *Alfreda Lee, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01013 (TVT-Secur);

18. *Angela Morrison, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00800 (TVT);

19. *Miranda Patterson v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00481 (TVT-O);

20. *Patti Ann Phelps v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01171 (TVT);

21. *Maria Eugenia Quijano v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00799 (TVT);

22. *Jennifer Reyes, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00939 (TVT);

23. *Ana Ruebel v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00663 (Prolift Total & TVT-O);

24. *Denise Sacchetti v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01148 (TVT-O);

25. *Stacy Shultis, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00654 (TVT-O);

26. *Susan Thaman v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00279 (Prolift Anterior & TVT-Secur);

27. *Laura Waynick, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01151 (TVT);

28. *Rebecca Wheeler, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01088 (TVT-O);

29. *Virginia White, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00958 (Gynemesh PS & TVT-R); and

30. *Kathleen Wolfe v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00337 (TVT).

* Defendants reserve the right to supplement this list should any other plaintiff be allowed to designate Dr. Blaivas as general causation expert in MDL Wave 1.

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Pending before the court is the Motion to Exclude or Limit the Opinions and Testimony of Dr. Salil Khandwala, M.D. [ECF No. 2003] filed by the plaintiffs. The Motion is now ripe for consideration because briefing is complete.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 75,000 cases currently pending, approximately 30,000 of which are in this MDL, which involves defendants Johnson & Johnson and Ethicon, Inc. (collectively "Ethicon"), among others.

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II. Preliminary Matters

Before plunging into the heart of the Motion, a few preliminary matters need to be addressed.

I am compelled to comment on the parties' misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of expert testimony based on its reliability and relevance. In other words, the parties have comparatively examined expert testimony and have largely overlooked *Daubert*'s core considerations for assessing expert

[1] The plaintiffs identified the Wave 1 cases affected by this Motion in their attached Exhibit A [ECF No. 2003-1], which the court has attached to this Memorandum Opinion and Order. At the time of transfer or remand, the parties will be required to designate relevant pleadings from MDL 2327, including the motion, supporting memorandum, response, reply, and exhibits referenced herein.

testimony. Although I recognize the tendency of my prior evidentiary determinations to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are misplaced, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper for the admission of expert testimony, as well as my duty to "respect[ ] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert testimony and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular expert testimony and objections currently before me, I assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the expert testimony contained therein.

Finally, I have attempted to resolve all possible disputes before transfer or remand, including those related to the admissibility of expert testimony pursuant to *Daubert*. Nevertheless, in some instances I face *Daubert* challenges where my interest in accuracy counsels reserving ruling until the reliability of the expert

testimony may be evaluated at trial. At trial, the expert testimony will be tested by precise questions asked and answered. The alternative of live *Daubert* hearings is impossible before transfer or remand because of the numerosity of such motions in these seven related MDLs. As these MDLs have grown and the expert testimony has multiplied, I have become convinced that the critical gatekeeping function permitting or denying expert testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert testimony offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of "junk science" looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalizations of expert testimony, and incomplete deposition transcripts. This, combined with the above-described practice of recycling expert testimony, objections, and the court's prior rulings, creates the perfect storm of obfuscation. Where further clarity is necessary, I believe it can only be achieved through live witness testimony—not briefing—and I will therefore reserve ruling until the expert testimony can be evaluated firsthand.

III. Legal Standard

By now, the parties should be intimately familiar with Rule 702 of the Federal Rules of Evidence and *Daubert*, so the court will not linger for long on these

standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

> (1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts "principles and methodology" above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g.*, *Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

IV. Discussion

Dr. Salil Khandwala is board-certified in obstetrics, gynecology, and female pelvic medicine and reconstructive surgery.

a. Safety and Efficacy

The plaintiffs challenge the reliability of Dr. Khandwala's expert testimony by criticizing the studies he chose to compare, opining he should have adjusted his criteria, noting his failure to account for varying definitions of "success," claiming he focuses on objective outcomes over subjective outcomes, and pointing out his failure to publish his own study. At bottom, the plaintiffs have not sufficiently supported their arguments or credibly called into question the reliability of this expert testimony. The plaintiffs are free to raise their concerns on cross-examination, but their Motion is **DENIED** on this point.

b. Mesh Properties

The plaintiffs also seek exclusion of Dr. Khandwala's testimony on biomaterials, biocompatibility, and foreign body response because he has "conceded" that he is not a biomaterials expert. Such concessions are not dispositive, particularly when taken out of context. Dr. Khandwala is a board-certified urogynecologist with a subspecialty in female pelvic medicine and reconstructive surgery. He has used polypropylene mesh in more than 1,000 SUI procedures and over 800 POP procedures. This extensive clinical experience qualifies Dr. Khandwala to opine on mesh's reaction to and effect on the human body from a clinical perspective. The plaintiffs' Motion is **DENIED** on this matter.

The plaintiffs also challenge the reliability of Dr. Khandwala's opinions on degradation and contraction. Ethicon acknowledges that Dr. Khandwala's expert report contains no degradation opinion and represents that he will not offer

degradation opinions at trial. The plaintiffs' Motion as to degradation is **DENIED as moot**.

As to contraction, Dr. Khandwala's opinion is supported by "extensive clinical experience and his analysis of the scientific literature." Resp. 9 [ECF No. 2175]. In the abstract, these are reliable bases on which to form an expert opinion. *See Kumho*, 526 U.S. at 156 ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience."). However, the court is unable to judge the reliability of Dr. Khandwala's observations without more information about his methodology. *See* Fed. R. Evid. 702 advisory committee's note to 2000 amendment ("If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts."). I am without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony based primarily on a doctor's clinical experience *not* observing something. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

The plaintiffs also seek to exclude Dr. Khandwala's testimony on mesh porosity and stiffness, though on what grounds is unclear. To the extent they are challenging Dr. Khandwala's qualifications, the Motion is **DENIED** for the reasons discussed above on biomaterials. To the extent they are challenging reliability, I **RESERVE** ruling for the reasons laid out above related to mesh contracture.

c. Warnings

Ethicon states that Dr. Khandwala will not testify at trial regarding the adequacy of the relevant Instructions for Use. Accordingly, the plaintiffs' Motion is **DENIED as moot** as to this matter.

V. Recurring Issues

Many of the *Daubert* motions filed in this MDL raise the same or similar objections.

One particular issue has been a staple in this litigation, so I find it best to discuss it in connection with every expert. A number of the *Daubert* motions seek to exclude FDA testimony and other regulatory or industry standards testimony. To the extent this Motion raises these issues it is **GRANTED in part** and **RESERVED in part** as described below.

I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs, and will continue to do so in these cases, a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913, 921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible prejudicial impact under Rule 403). Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See In re C. R. Bard*, 81 F.3d at 920 ("[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value."). Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors "to erroneously

conclude that regulatory compliance proved safety." *Id.* at 922. Accordingly, expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, is **EXCLUDED**. For the same reasons, opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations are **EXCLUDED**. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue in these cases and runs the risk of misleading the jury and confusing the issues. Insofar as this Motion challenges the FDA-related testimony discussed here, the Motion is **GRANTED**.

A number of experts also seek to opine on Ethicon's compliance with design control and risk management standards. Some of this testimony involves the FDA's quality systems regulations, and some—likely in an attempt to sidestep my anticipated prohibition on FDA testimony—involve foreign regulations and international standards. I find all of this proposed testimony of dubious relevance. Although these standards relate to how a manufacturer should structure and document risk assessment, the standards do not appear to mandate any particular design feature or prescribe the actual balance that must be struck in weighing a product's risk and utility. Nor is it clear that the European and other international standards discussed had any bearing on the U.S. medical device industry when the device in question was being designed.

Nevertheless, because the nuances of products liability law vary by state, I will

refrain from issuing a blanket exclusion on design process and control standards testimony, whether rooted in the FDA or otherwise. Each standard must be assessed for its applicability to the safety questions at issue in this litigation, consistent with state law. I am without sufficient information to make these findings at this time. Accordingly, I **RESERVE** ruling on such matters until a hearing, where the trial judge will have additional context to carefully evaluate the relevance and potential prejudicial impact of specific testimony.

Similarly, I doubt the relevance of testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by the above discussion. Again, such matters seem to say very little about the state of the product itself (i.e., whether or not it was defective) when it went on the market. But because the scope of relevant testimony may vary according to differences in state products liability law, I **RESERVE** ruling on such matters until they may be evaluated in proper context at a hearing before the trial court before or at trial.

Additional—and more broad—matters also warrant mention. While some of these concerns may not apply to this particular expert, these concerns are raised so frequently that they are worth discussing here.

First, many of the motions seek to exclude state-of-mind and legal-conclusion expert testimony. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury's fact-finding function by allowing testimony of this type, and I do the same here. *E.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611

(S.D. W. Va. 2013); *see also, e.g.*, *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) ("Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony."). Additionally, an expert may not offer expert testimony using "legal terms of art," such as "defective," "unreasonably dangerous," or "proximate cause." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

Second, and on a related note, many of the motions seek to prohibit an expert from parroting facts found in corporate documents and the like. I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his or her review of internal corporate documents solely for the purpose of explaining the basis for his or her expert opinions—assuming the expert opinions are otherwise admissible—he or she may not offer testimony that is solely a conduit for corporate information.

Third, many of the motions also ask the court to require an expert to offer testimony consistent with that expert's deposition or report or the like. The court will not force an expert to testify one way or another. To the extent an expert offers inconsistent testimony, the matter is more appropriately handled via cross-examination or impeachment as appropriate and as provided by the Federal Rules of Evidence.

Fourth, in these *Daubert* motions, the parties have addressed tertiary

evidentiary matters like whether certain statements should be excluded as hearsay. The court will not exclude an expert simply because a statement he or she discussed may constitute hearsay. *Cf. Daubert*, 509 U.S. at 595. Hearsay objections are more appropriately raised at trial.

Finally, in some of the *Daubert* motions, without identifying the specific expert testimony to be excluded, the parties ask the court to prevent experts from offering testimony the expert is not qualified to offer. I will not make speculative or advisory rulings. I decline to exclude testimony where the party seeking exclusion does not provide specific content or context.

VI. Conclusion

The court **DENIES in part**, **GRANTS in part**, and **RESERVES in part** the Motion to Exclude or Limit the Opinions and Testimony of Dr. Salil Khandwala, M.D. [ECF No. 2003].

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 1 cases identified in the Exhibit attached hereto.

ENTER: September 2, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

EXHIBIT A – KHANDWALA DAUBERT MOTION

Brenda Riddell
Case No. 2:12-cv-00547

Dina Sanders Bennett
Case No. 2:12-cv-00497

Beverly Kivel
Case No. 2:12-cv-00591

Barbara Kaiser
Case No. 2:12-cv-00887

Shirley Walker
Case No. 2:12-cv-00873

Pamela Free
Case No. 2:12-cv-00423

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION MDL No. 2327

THIS DOCUMENT RELATES TO:

Cases Identified in the Exhibit
Attached Hereto

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Dr. Jimmy W. Mays)

Pending before the court is the Motion to Exclude the Opinions and Testimony of Dr. Jimmy W. Mays [ECF No. 2071] filed by the defendants Ethicon, Inc. and Johnson & Johnson (collectively "Ethicon"). The Motion is ripe for consideration.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 75,000 cases currently pending, approximately 30,000 of which are in this MDL.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict*

Litigation in Products Liability Cases 3 (2011). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure. In Pretrial Order ("PTO") No. 217, the court instructed the parties to file only one *Daubert* motion per challenged expert, to file each motion in the main MDL—as opposed to the individual member cases—and to identify which cases would be affected by the motion. PTO No. 217, at 4.[1]

II. Preliminary Matters

Before plunging into the heart of the Motion, a few preliminary matters need to be addressed.

I am compelled to comment on the parties' misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of expert testimony based on its reliability and relevance. In other words, the parties have comparatively examined expert testimony and have largely overlooked *Daubert*'s core considerations for assessing expert testimony. Although I recognize the tendency of my prior evidentiary determinations

[1] Ethicon identified the Wave 1 cases affected by this Motion in its Exhibit A [ECF No. 2071-1], which the court has attached to this Memorandum Opinion and Order. At the time of transfer or remand, the parties will be required to designate relevant pleadings from MDL 2327, including the motion, supporting memorandum, response, reply, and exhibits referenced herein.

to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are misplaced, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper for the admission of expert testimony, as well as my duty to "respect[ ] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert testimony and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular expert testimony and objections currently before me, I assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the expert testimony contained therein.

Finally, I have attempted to resolve all possible disputes before transfer or remand, including those related to the admissibility of expert testimony pursuant to *Daubert*. Nevertheless, in some instances I face *Daubert* challenges where my interest in accuracy counsels reserving ruling until the reliability of the expert testimony may be evaluated at trial. At trial, the expert testimony will be tested by

precise questions asked and answered. The alternative of live *Daubert* hearings is impossible before transfer or remand because of the numerosity of such motions in these seven related MDLs. As these MDLs have grown and the expert testimony has multiplied, I have become convinced that the critical gatekeeping function permitting or denying expert testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert testimony offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of "junk science" looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalizations of expert testimony, and incomplete deposition transcripts. This, combined with the above-described practice of recycling expert testimony, objections, and the court's prior rulings, creates the perfect storm of obfuscation. Where further clarity is necessary, I believe it can only be achieved through live witness testimony—not briefing—I will therefore reserve ruling until expert testimony can be evaluated firsthand.

III. Legal Standard

By now, the parties should be intimately familiar with Rule 702 of the Federal Rules of Evidence and *Daubert*, so the court will not linger for long on these standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

> (1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts "principles and methodology" above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g.*, *Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

IV. Discussion

Dr. Mays has a Ph.D. in polymer science and is an expert witness for the plaintiffs. Ethicon objects to Dr. Mays's expert testimony on several grounds discussed below.

a. Degradation

Ethicon argues that Dr. Mays's degradation opinions are unreliable and should be excluded. Ethicon's argument hinges on its assertion that Prolene is unique from generic polypropylene and Dr. Mays did not base his opinions on literature specific to Prolene. I disagree that the supposed distinction between Prolene specifically and polypropylene generally renders studies on the latter unhelpful when discussing the former. *See, e.g.*, *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 703 (S.D. W. Va. 2014) (rejecting Ethicon's argument as "wholly conceived by lawyers, unfounded in science"). Insofar as Ethicon seeks exclusion of Dr. Mays's opinions because he does not account for the differences between polypropylene and Prolene, its Motion is **DENIED**.[2]

I also reject the argument that Dr. Mays should not be permitted to base his opinion on internal Ethicon studies on Prolene sutures unless Ethicon can introduce evidence of FDA approval. FDA approval of Prolene sutures has no bearing on the degradation-specific findings of the relevant studies or on the appropriateness of Dr. Mays's reliance on them to opine on degradation. Ethicon's Motion to this effect is **DENIED**.

b. Complications

Ethicon also seeks to exclude Dr. Mays's opinions regarding medical

[2] The court views Ethicon's concerns that Dr. Mays did not conduct his own testing or rely on appropriate literature as stemming from its contention that Prolene is incomparable to generic polypropylene. Such arguments are disposed of in the above ruling.

complications that are caused by alleged mesh degradation. Dr. Mays is not a medical doctor; instead, he is a polymer chemist. Dr. Mays has not examined patients, and he has not conducted differential diagnoses. Dr. Mays is simply not qualified to offer opinions on medical complications that may be caused by polymer degradation. Accordingly, Dr. Mays's opinions regarding complications resulting from alleged polypropylene degradation are **EXCLUDED**.

V. Recurring Issues

Many of the *Daubert* motions filed in this MDL raise the same or similar objections.

One particular issue has been a staple in this litigation, so I find it best to discuss it in connection with every expert. A number of the *Daubert* motions seek to exclude FDA testimony and other regulatory or industry standards testimony. To the extent this Motion raises these issues it is **GRANTED in part** and **RESERVED in part** as described below.

I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs, and will continue to do so in these cases, a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913, 921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible prejudicial impact under Rule 403). Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See In re C. R. Bard,* 81 F.3d at 920 ("[T]he clear weight of persuasive and controlling authority

favors a finding that the 510(k) procedure is of little or no evidentiary value."). Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors "to erroneously conclude that regulatory compliance proved safety." *Id.* at 922. Accordingly, expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, is **EXCLUDED**. For the same reasons, opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations are **EXCLUDED**. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue in these cases and runs the risk of misleading the jury and confusing the issues. Insofar as this Motion challenges the FDA-related testimony discussed here, the Motion is **GRANTED**.

A number of experts also seek to opine on Ethicon's compliance with design control and risk management standards. Some of this testimony involves the FDA's quality systems regulations, and some—likely in an attempt to sidestep my anticipated prohibition on FDA testimony—involve foreign regulations and international standards. I find all of this proposed testimony of dubious relevance. Although these standards relate to how a manufacturer should structure and document risk assessment, the standards do not appear to mandate any particular design feature or prescribe the actual balance that must be struck in weighing a product's risk and utility. Nor is it clear that the European and other international

standards discussed had any bearing on the U.S. medical device industry when the device in question was being designed.

Nevertheless, because the nuances of products liability law vary by state, I will refrain from issuing a blanket exclusion on design process and control standards testimony, whether rooted in the FDA or otherwise. Each standard must be assessed for its applicability to the safety questions at issue in this litigation, consistent with state law. I am without sufficient information to make these findings at this time. Accordingly, I **RESERVE** ruling on such matters until a hearing, where the trial judge will have additional context to carefully evaluate the relevance and potential prejudicial impact of specific testimony.

Similarly, I doubt the relevance of testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by the above discussion. Again, such matters seem to say very little about the state of the product itself (i.e., whether or not it was defective) when it went on the market. But because the scope of relevant testimony may vary according to differences in state products liability law, I **RESERVE** ruling on such matters until they may be evaluated in proper context at a hearing before the trial court or at trial.

Additional—and more broad—matters also warrant mention. While some of these concerns may not apply to this particular expert, these concerns are raised so frequently that they are worth discussing here.

First, many of the motions seek to exclude state-of-mind and legal-conclusion

expert testimony. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury's fact-finding function by allowing testimony of this type, and I do the same here. *E.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g.*, *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) ("Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony."). Additionally, an expert may not offer expert testimony using "legal terms of art," such as "defective," "unreasonably dangerous," or "proximate cause." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

Second, and on a related note, many of the motions seek to prohibit an expert from parroting facts found in corporate documents and the like. I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his or her expert opinions—assuming the expert testimony is otherwise admissible—he or she may not offer testimony that is solely a conduit for corporate information.

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examination or impeachment as appropriate and as provided by the Federal Rules of Evidence.

Fourth, in these *Daubert* motions, the parties have addressed tertiary evidentiary matters like whether certain statements should be excluded as hearsay. The court will not exclude an expert simply because a statement he or she discussed may constitute hearsay. *Cf. Daubert*, 509 U.S. at 595. Hearsay objections are more appropriately raised at trial.

Finally, in some of the *Daubert* motions, without identifying the specific expert testimony to be excluded, the parties ask the court to prevent experts from offering other expert testimony that the moving party claims the expert is not qualified to offer. I will not make speculative or advisory rulings. I decline to exclude testimony where the party seeking exclusion does not provide specific content or context.

VI. Conclusion

The court **DENIES in part**, **GRANTS in part**, and **RESERVES in part** the Motion to Exclude the Opinions and Testimony of Dr. Jimmy W. Mays [ECF No. 2071].

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 1 cases identified in the Exhibit attached hereto.

ENTER: August 25, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

EXHIBIT - MAYS

Case Name	Case Number
Blake, Bonnie & Larry Miketey	2:12cv00995
Bridges, Robin	2:12cv00651
Cole, Carey Beth & David	2:12cv00483
Coleman, Angela & Timothy	2:12cv01267
Destefano-Raston, Dina & Terry	2:12cv01299
Dixon, Dennis W., re estate of Virginia M. Dixon, dec'd	2:12cv01081
Drake, Karyn E. & Douglas E.	2:12cv00747
Evans, Ida Deanne	2:12cv01225
Fisk, Paula	2:12cv00848
Free, Pamela	2:12cv00423
Georgilakis, Teresa & Angelo	2:12cv00829
Grabowski, Louise	2:12cv00683
Hankins, Dawna	2:12cv00783 369
Hooper, Nancy & Daniel	2:12cv00493
Lee, Alfreda & James	2:12cv01013
Lozano, Deborah & Felipe	2:12cv00347
Padilla, Noemi	2:12cv00567
Reyes, Jennifer & Jerry	2:12cv00939
Sikes, Jennifer	2:12cv00501
Smith, Carrie	2:12cv00258
Swint, Isabel	2:12cv00786
Teasley, Krystal	2:12cv00500
Thaman, Susan	2:12cv00279
Thomas, Kimberly	2:12cv00499
Vignos-Ware, Barbara J. & Gary L.	2:12cv00761
Warlick, Cathy	2:12cv00276
~~Wilson, Blynn~~ Wolfe, Elizabeth Blynn	2:12cv01286
Wroble, Julie & Jerry	2:12cv01090

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION MDL No. 2327

THIS DOCUMENT RELATES TO:

Wave 2 Cases Identified in the
Exhibit Attached Hereto

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Larry T. Sirls, M.D.)

Pending before the court is the Motion to Exclude the General Opinion and Testimony of Larry T. Sirls, II, M.D. [ECF No. 2479] filed by the plaintiffs. The Motion is now ripe for consideration because briefing is complete.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 60,000 cases currently pending, approximately 28,000 of which are in this MDL, which involves defendants Johnson & Johnson and Ethicon, Inc. (collectively "Ethicon"), among others.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict*

Litigation in Products Liability Cases 3 (2011). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure. In Pretrial Order ("PTO") No. 206, the court instructed the parties to file only one *Daubert* motion per challenged expert, to file each motion in the main MDL—as opposed to the individual member cases—and to identify which cases would be affected by the motion.[1]

II. Preliminary Matters

Before plunging into the heart of the Motion, a few preliminary matters need to be addressed.

I am compelled to comment on the parties' misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of expert testimony based on its reliability and relevance. In other words, the parties have comparatively examined expert testimony and have largely overlooked *Daubert*'s core considerations for assessing expert testimony. Although I recognize the tendency of my prior evidentiary determinations to influence subsequent motions practice, counsels' expectations that I align with

[1] On Exhibit A, I have marked through cases that are closed, on the inactive docket, not in Wave 2, could not be identified because of an error in the style or case number, or assigned to another District Judge.

these previous rulings when faced with a different record are misplaced, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper for the admission of expert testimony, as well as my duty to "respect[ ] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert testimony and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular expert testimony and objections currently before me, I assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the expert testimony contained therein.

Finally, I have attempted to resolve all possible disputes before transfer or remand, including those related to the admissibility of expert testimony pursuant to *Daubert*. Nevertheless, in some instances I face *Daubert* challenges where my interest in accuracy counsels reserving ruling until the reliability of the expert testimony may be evaluated at trial. At trial, the expert testimony will be tested by precise questions asked and answered. The alternative of live *Daubert* hearings is

impossible before transfer or remand because of the numerosity of such motions in these seven related MDLs. As these MDLs have grown and the expert testimony has multiplied, I have become convinced that the critical gatekeeping function permitting or denying expert testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert testimony offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of "junk science" looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalizations of expert testimony, and incomplete deposition transcripts. This, combined with the above-described practice of recycling expert testimony, objections, and the court's prior rulings, creates the perfect storm of obfuscation. Where further clarity is necessary, I believe it can only be achieved through live witness testimony—not briefing—I will therefore reserve ruling until expert testimony can be evaluated firsthand.

III. Legal Standard

By now, the parties should be intimately familiar with Rule 702 of the Federal Rules of Evidence and *Daubert*, so the court will not linger for long on these standards.

Expert testimony is admissible if the expert is qualified and if his or her expert

testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

> (1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts "principles and methodology" above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g.*, *Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

IV. Discussion

Many of the *Daubert* motions filed in this MDL raise the same or similar objections.

One particular issue has been a staple in this litigation, so I find it best to discuss it in connection with every expert. A number of the *Daubert* motions seek to

exclude FDA testimony and other regulatory or industry standards testimony. To the extent this Motion raises these issues it is **GRANTED in part** and **RESERVED in part** as described below.

I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs, and will continue to do so in these cases, a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913, 921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible prejudicial impact under Rule 403). Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See In re C. R. Bard*, 81 F.3d at 920 ("[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value."). Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors "to erroneously conclude that regulatory compliance proved safety." *Id.* at 922. Accordingly, expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, is **EXCLUDED**. For the same reasons, opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations are **EXCLUDED**. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue in these cases and runs the risk of misleading the jury and confusing the issues.

Insofar as this Motion challenges the FDA-related testimony discussed here, the Motion is **GRANTED**.

A number of experts also seek to opine on Ethicon's compliance with design control and risk management standards. Some of this testimony involves the FDA's quality systems regulations, and some—likely in an attempt to sidestep my anticipated prohibition on FDA testimony—involve foreign regulations and international standards. I find all of this proposed testimony of dubious relevance. Although these standards relate to how a manufacturer should structure and document risk assessment, the standards do not appear to mandate any particular design feature or prescribe the actual balance that must be struck in weighing a product's risk and utility. Nor is it clear that the European and other international standards discussed had any bearing on the U.S. medical device industry when the device in question was being designed.

Nevertheless, because the nuances of products liability law vary by state, I will refrain from issuing a blanket exclusion on design process and control standards testimony, whether rooted in the FDA or otherwise. Each standard must be assessed for its applicability to the safety questions at issue in this litigation, consistent with state law. I am without sufficient information to make these findings at this time. Accordingly, I **RESERVE** ruling on such matters until a hearing where the trial judge will have additional context to carefully evaluate the relevance and potential prejudicial impact of specific testimony.

Similarly, I doubt the relevance of testimony on the adequacy of Ethicon's

clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by the above discussion. Again, such matters seem to say very little about the state of the product itself (i.e., whether or not it was defective) when it went on the market. But because the scope of relevant testimony may vary according to differences in state products liability law, I **RESERVE** ruling on such matters until they may be evaluated in proper context at a hearing before the trial court before or at trial.

Additional—and more broad—matters also warrant mention. While some of these concerns may not apply to this particular expert, these concerns are raised so frequently that they are worth discussing here.

First, many of the motions seek to exclude state-of-mind and legal-conclusion expert testimony. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury's fact-finding function by allowing testimony of this type, and I do the same here. *E.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g.*, *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) ("Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony."). Additionally, an expert may not offer expert testimony using "legal terms of art," such as "defective," "unreasonably dangerous," or "proximate cause." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

Second, and on a related note, many of the motions seek to prohibit an expert from parroting facts found in corporate documents and the like. I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his or her expert opinions—assuming the expert opinions are otherwise admissible—he or she may not offer testimony that is solely a conduit for corporate information.

Third, many of the motions also ask the court to require an expert to offer testimony consistent with that expert's deposition or report or the like. The court will not force an expert to testify one way or another. To the extent an expert offers inconsistent testimony, the matter is more appropriately handled via cross-examination or impeachment as appropriate and as provided by the Federal Rules of Evidence.

Fourth, in these *Daubert* motions, the parties have addressed tertiary evidentiary matters like whether certain statements should be excluded as hearsay. The court will not exclude an expert simply because a statement he or she discussed may constitute hearsay. *Cf. Daubert*, 509 U.S. at 595. Hearsay objections are more appropriately raised at trial.

Finally, in some of the *Daubert* motions, without identifying the specific expert testimony to be excluded, the parties ask the court to prevent experts from offering other expert testimony that the moving party claims the expert is not qualified to offer. I will not make speculative or advisory rulings. I decline to exclude testimony

where the party seeking exclusion does not provide specific content or context.

V. Remaining Issues

I **FIND** that the remaining issues contained in the plaintiffs' Motion are better suited for cross-examination. Accordingly, except as otherwise stated in this Memorandum Opinion & Order, the plaintiffs' Motion is **DENIED** in all other respects.

VI. Conclusion

The court **DENIES in part**, **GRANTS in part** and **RESERVES in part** the Motion to Exclude the General Opinion and Testimony of Larry T. Sirls, II, M.D. [ECF No. 2479].

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 2 cases identified in the Exhibit attached hereto.

ENTER: March 29, 2017

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

EXHIBIT A

Case	Civil Action Number
~~Ankenman, Cathleen & John J.~~	~~2:12cv00872~~
Kowalski, Judith Mary	2:12cv01323
Hart, Mary Ann & William J.	2:12cv01326
Schroeder, Carreen & Matthew	2:12cv01327
Almendarez, Angela M.	2:12cv01329
~~Hines, Lynn & Gregory~~	~~2:12cv01331~~
Rose, Lola	2:12cv01336
Vandergriff, Debbie & Carl	2:12cv01342
Eaton, Cynthia & Frank	2:12cv01348
Aldrich, Jacqueline Marie & Darryl	2:12cv01364
Higgins, Susan & Bob	2:12cv01365
McDonald, Maria & Thomas	2:12cv01366
~~Glasgow, Carol~~	~~2:12cv01367~~
Valle, Maritza	2:12cv01368
~~Thomas, Mary~~	~~2:12cv01370~~
Fitzgerald, Alina & Christopher	2:12cv01371
Boudreau, Linda L. & Charles J.	2:12cv01373
Simpson, Sherry Gill & Ricky	2:12cv01414
~~Watson, Sandra Rosalie & Earl L.~~	~~2:12cv01426~~
~~Brady, Victoria Lee & Maurice Joseph~~	~~2:12cv01428~~
~~Mickle, Karen~~	~~2:12cv01432~~
Grayson, Pamela Sue	2:12cv01435
Pocztowski, Debra	2:12cv01470
Perry, Mary Lou	2:12cv01477
~~Ford, Deborah K. & Donald K. Blowers, Jr.~~	~~2:12cv01486~~
Brown, Valerie	2:12cv01489
Blackston, Ossie & John	2:12cv01493
~~Martin, Diann & Donald~~	~~2:12cv01495~~
Schomer, Margaret A.	2:12cv01497
~~Smith, Patricia G. & Mark~~	~~2:12cv01498~~
~~Cruse, Peggy D.~~	~~2:12cv01501~~
~~Raney, Barbara A. & Marcus~~	~~2:12cv01507~~
Espinoza, Rhondi	2:12cv01517
Majors, Jennifer A. & Jonathan S.	2:12cv01523
~~Flanigan, Iris & Earl David~~	~~2:12cv01524~~
~~Gologan, Didina & Alexandru~~	~~2:12cv01528~~
~~Burton, Kimberly Lee & Christopher Carl~~	~~2:12cv01529~~

Chase, Alvette	2:12cv01533
McGathey, Elizabeth M.	2:12cv01538
Ferguson, Teresa	2:12cv01544
~~Crews, Lillie Harriet & Wain E.~~	~~2:12cv01549~~
~~Spitzner, Bobbie Dianne & James W.~~	~~2:12cv01552~~
~~Sanders, Melissa & Charles, Jr.~~	~~2:12cv01562~~
Amidei, Betty	2:12cv01563
~~Childress, Sandra & Timothy~~	~~2:12cv01564~~
~~Cottrell, Teresa & Joe Palazzolo~~	~~2:12cv01565~~
~~Harper, Kathy~~	~~2:12cv01567~~
~~Wilson, Marcia & Robert~~	~~2:12cv01568~~
Rasos, Katherine	2:12cv01599
~~Walkingstick, Margaret Christine~~	~~2:12cv01616~~
~~Smythia, Rebecca~~	~~2:12cv01622~~
~~Smith, Andora~~	~~2:12cv01623~~
Lindberg, Patricia & Carl	2:12cv01637
Perez, Leezel & Jeffrey	2:12cv01640
~~Cole, Phyllis Smith & Willie Ray~~	~~2:12cv01645~~
~~Guffey, Gail~~	~~2:12cv01650~~
Hatfield, Nona & Billy Ray	2:12cv01657
Moore, Phyllis	2:12cv01659
~~Cooper, Jennifer & Dave~~	~~2:12cv01660~~
Carter, Tamara & David	2:12cv01661
~~Smallwood, Nancy & Leon, Sr.~~	~~2:12cv01662~~
~~Glenn, Rhonda & Era Fox, III~~	~~2:12cv01663~~
Allen, Diana & Timothy	2:12cv01676
Fleck, Jean E.	2:12cv01681
Lenz, Debera & Robert	2:12cv01692
~~Mooney, Konnie L. & James~~	~~2:12cv01695~~
Miller, Mona	2:12cv01696
Bailey, Pamela & Houston	2:12cv01700
Cedeno, Joyce	2:12cv01701
Colbert, Rhonda & Joseph	2:12cv01702
Hoch, Susan & Christopher	2:12cv01703
Johnson, Cynthia & Robert	2:12cv01704
Meyer, Linda & Steve	2:12cv01705
Muir, Marilyn & Scott	2:12cv01706
Shelton, Mary & Frank	2:12cv01707
Shennum, Janice	2:12cv01708
~~Swanson, Karen & Thomas~~	~~2:12cv01709~~
Parker, Belinda	2:12cv01710

Hutchison, Deanna Gail	2:12cv01711
Suter, Carol Ann & Troy W.	2:12cv01712
Denton, Shirley & Marvin	2:12cv01719
Frazier, Margaret & William Allen	2:12cv01731
Raines, Myra & Kenneth	2:12cv01735
Rhodes, Rebecca & Scott	2:12cv01736
Sidwell, Loretta & Jimmy	2:12cv01737
Williamson, Betty & Donald	2:12cv01739
Gibson, Susan & Michael	2:12cv01740
Savage, Stacey D. & Ebbie E. Ferrell	2:12cv01743
Blevins, Vickie Lea & Robert Oliver	2:12cv01746
Slade, Sebrina & Eric	2:12cv01753
Paris, Christin & Michael	2:12cv01759
Young, Tina L. & Jeffrey	2:12cv01772
Patrick, Lottie M. & John D.	2:12cv01776
Lane, Ann Jennette & Daniel Mark	2:12cv01785
Cutter, Jenesta & Larry A.	2:12cv01790
Burnett, Mary K.	2:12cv01795
Heuer, Myra	2:12-cv-01796
Hammett, Carolyn R.	2:12cv01802
Brookman, Lesley Mitchell & Michael	2:12cv01803
Merten, Janet & Gerard	2:12cv01817
Zutovsky, Linda & Leonard	2:12cv01818
Sierra, Ana & Luis	2:12cv01819
Hemingway, Veda & Gary	2:12cv01829
Strickland, Deborah J. & Matthew	2:12cv01830
Guy, Sheryl C.	2:12cv01831
Gray, Wanda	2:12cv01832
Abell, Emily S. & Michael K.	2:12cv01833
Bishop, Cheryl L.	2:12cv01834
Symank, Bernie & Herman	2:12cv01836
Franklin, Betty	2:12cv01837
Gallehugh, Michelle & Ronnie	2:12cv01838
Parton, Lori Anne Copeland, Executrix of the Estate of Sue Bilbrey Copeland, deceased	2:12cv01848
Peterson, Winnie Elise	2:12cv01849
Jernigan, Joan E. & Fred T.	2:12cv01850
Luna, Tracy L.	2:12cv01853
Hays, Brenda & Roger	2:12cv01855
Sutton, Martha	2:12cv01857
Hensley, Mary M.	2:12cv01858

Bowles, Phyllis & Charles	2:12cv01865
Rogers, Ruby G. & Dwayne L.	2:12cv01877
Irwin, Priscilla A. & Daniel S.	2:12cv01878
Dycus, Myrtle Frances	2:12cv01879
Henry, Lana & Phillip Dean	2:12cv01938
Garland, Marian	2:12cv01939
Young-Poole, Brenda	2:12cv01962
Riggs, Donna & Gary	2:12cv01967
Zapata, Sandra	2:12cv01972
Slocumb, Kathryn	2:12cv01974
Hughes, Brenda L. & Ronnie	2:12cv01976
Poole, Cheryl & Kenneth	2:12cv01978
Devoe, Debra & Randy	2:12cv01979
Moon, Carolyn	2:12cv01980
Covington-Branker, Barbara M. & Brian B.	2:12cv01983
Cope, Michele A. & Barry	2:12cv01984
Deforrest, Patricia Ann & John H.	2:12cv01985
Cambre, Terri L.	2:12cv01986
Trimper, Carolyn S.	2:12cv01987
West, Peggy Sue & Larry R.	2:12cv01988
Phillips, Eleanor F. & John R.	2:12cv01989
Higgins, Anna R.	2:12cv01990
Brennon, Rebecca J.	2:12cv01995
Carr, Gwendolyn N. & Rundell D.	2:12cv01996
Bates, Diane	2:12cv02020
Bowers, Betty Jean	2:12cv02022
Beard, Gavie & Kenneth	2:12cv02025
Carroll, Margaret	2:12cv02026
Gullett, Brenda & Carl	2:12cv02027
Maddox, Brenda	2:12cv02028
Martin, Phyllis	2:12cv02029
Peterson, Tracy & Kevin	2:12cv02030
Reed, Deborah F. & Dale K.	2:12cv02059
Chrysler, Marion	2:12cv02060
Heddle, Bridget	2:12cv02071
Pratt, Cathy	2:12cv02072
Hernandez, Toni	2:12cv02073
Dawson, Kristen	2:12cv02074
Daugherty, Angela & Jimmy	2:12cv02076
Marshall, Natalie C. & David R.	2:12cv02077
Hand, Wanda M. & Charles W.	2:12cv02079

Burns-Martin, Dayna & Kevin	2:12cv02081
Brady, Deborah D.	2:12-cv-02086
Hicks, Shannon H. & James D.	2:12cv02094
McClain, Barbara Sue	2:12cv02095
Roberts, Brenda C. & Dwight	2:12cv02096
Clay, Crystal Lynn	2:12cv02097
Wilson, Tina	2:12cv02099
Scott, Teresa	2:12cv02100
Bishop, Jessie	2:12cv02101
Whinery, Joyce	2:12cv02102
Nelson, Kathryn M.	2:12cv02103
Loomis, Barbara & Dighton	2:12cv02104
Minogue, Bridgette	2:12cv02112
Doucette, Karen L.	2:12cv02125
Dunham, Lynne & David	2:12cv02131
Ursini, Tara	2:12cv02132
Anderson, Elaine	2:12cv02134
Crabtree, Reba & Jack	2:12cv02135
Lary, Sheryl & Kevin E.	2:12cv02136
Manor, Kristy & John E., III	2:12cv02137
Maxwell, Bonnie	2:12cv02138
Lewis, Marlene	2:12cv02139
Messina, Laritza & John	2:12cv02140
Morrison, Laura	2:12cv02141
Panske-Phillips, Emma & Luther Y., Jr.	2:12cv02142
Phillips, Ramona	2:12cv02143
Pitts, Michelle	2:12cv02144
Green, Janice	2:12cv02148
Pippin, Laura & Donald	2:12cv02152
Bihlmeyer, Donna & Joe	2:12cv02159
Semere, Yvonne	2:12cv02160
Hreiz, Amy Elizabeth & Adel Elias	2:12cv02165
Villarreal, Katherine & Carlos	2:12cv02167
Ogletree, Linda J. & John A.	2:12cv02168
Partin, Patricia Graham	2:12cv02179
Pageau, Tina Marie	2:12cv02180
Lambert, Corrie Ann & Ronson	2:12cv02183
Martin, Patricia J. & Dennis R., Sr.	2:12cv02185
Miller, Rose M.	2:12cv02187
Pieper, Laura & Mike	2:12cv02189
Pridmore, Hope Elaine & James O.	2:12cv02190

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Pending before the court is the Motion to Exclude the Opinions and Testimony of Shelby Thames [ECF No. 2039] filed by the plaintiffs. The Motion is now ripe for consideration because briefing is complete.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 75,000 cases currently pending, approximately 30,000 of which are in this MDL, which involves defendants Johnson & Johnson and Ethicon, Inc. (collectively "Ethicon"), among others.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict*

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II. Preliminary Matters

Before plunging into the heart of the Motion, a few preliminary matters need to be addressed.

I am compelled to comment on the parties' misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of expert testimony based on its reliability and relevance. In other words, the parties have comparatively examined expert testimony and have largely overlooked *Daubert*'s core considerations for assessing expert testimony. Although I recognize the tendency of my prior evidentiary determinations

[1] The plaintiffs identified the Wave 1 cases affected by this Motion in their attached Exhibit A [ECF No. 2039-1], which the court has attached to this Memorandum Opinion and Order. At the time of transfer or remand, the parties will be required to designate relevant pleadings from MDL 2327, including the motion, supporting memorandum, response, reply, and exhibits referenced herein.

to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are misplaced, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper for the admission of expert testimony, as well as my duty to "respect[ ] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert testimony and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular expert testimony and objections currently before me, I assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the expert testimony contained therein.

Finally, I have attempted to resolve all possible disputes before transfer or remand, including those related to the admissibility of expert testimony pursuant to *Daubert*. Nevertheless, in some instances I face *Daubert* challenges where my interest in accuracy counsels reserving ruling until the reliability of the expert testimony may be evaluated at trial. At trial, the expert testimony will be tested by

precise questions asked and answered. The alternative of live *Daubert* hearings is impossible before transfer or remand because of the numerosity of such motions in these seven related MDLs. As these MDLs have grown and the expert testimony has multiplied, I have become convinced that the critical gatekeeping function permitting or denying expert testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert testimony offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of "junk science" looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalizations of expert testimony, and incomplete deposition transcripts. This, combined with the above-described practice of recycling expert testimony, objections, and the court's prior rulings, creates the perfect storm of obfuscation. Where further clarity is necessary, I believe it can only be achieved through live witness testimony—not briefing—I will therefore reserve ruling until expert testimony can be evaluated firsthand.

III. Legal Standard

By now, the parties should be intimately familiar with Rule 702 of the Federal Rules of Evidence and *Daubert*, so the court will not linger for long on these standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

> (1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts "principles and methodology" above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g.*, *Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

IV. Discussion

Dr. Thames is a polymer chemist with a Ph.D. in organic chemistry. In 1969, Dr. Thames founded the Department of Polymer Science at the University of Southern Mississippi, and he has served as the Dean of the College of Science. Dr.

Thames's has researched and designed polymers for various uses.

a. Properties

First, the plaintiffs challenge multiple statements made in Dr. Thames's expert report that are related to degradation and the support—or lack thereof—found in Ethicon's seven-year dog study. The plaintiffs argue that this testimony is unreliable because Dr. Thames contradicts himself and misstates the study's findings. I do not find any of Dr. Thames's supposed self-contradictions to warrant exclusion. Nor is Dr. Thames's testimony unreliably contradictory to the extent it uses the dog study to support his opinion that Prolene "does not undergo meaningful or harmful degradation *in vivo*." Thames Report 6 [ECF No. 2039-3]. I do agree, however, with the plaintiffs' argument that Dr. Thames has occasionally misstated the dog study's specific findings as to molecular weight. Specifically, although the study reported no *significant* difference in molecular weights, Dr. Thames reports the study as finding *no* molecular weight change. *See, e.g.*, Thames Report 9. Insofar as Dr. Thames's testimony mischaracterizes the dog study's results on molecular weight change, it is **EXCLUDED** and the plaintiffs' Motion on this point is **GRANTED**.

Second, the plaintiffs challenge the reliability of Dr. Thames's opinion that the data collected from the seven-year dog study "validates toughness improvement after initial implantation." Mem. 5 [ECF No. 2042] (citing Thames Report 9). The plaintiffs disagree with the manner in which Dr. Thames has defined and measured "toughness." But the plaintiffs provide no support for their differing conception of the term or how it is most appropriately measured. Additionally, a review of Dr. Thames's

expert report and Ethicon's Response shows that he used a systematic method to plot data collected in the dog study on strength and elongation that could reasonably be said to relate to toughness. Accordingly, the plaintiffs' Motion on this matter is **DENIED**.

Third, the plaintiffs challenge Dr. Thames's opinions on translucent flakes detected on Prolene explants and the presence of extrusion lines. These opinions, however, are apparently contained in Dr. Thames's case-specific expert report regarding a particular Wave 1 plaintiff. As such, these objections are not appropriately addressed in the instant *Daubert* motion, which was filed in the main MDL and should challenge general causation opinions only. The plaintiffs' Motion on this matter is **DENIED**. Further, the plaintiffs' Motion, insofar as it relates to the cleaning protocol employed by Dr. Thames in his plaintiff-specific examination of mesh, is similarly **DENIED**.

V. Recurring Issues

Many of the *Daubert* motions filed in this MDL raise the same or similar objections.

One particular issue has been a staple in this litigation, so I find it best to discuss it in connection with every expert. A number of the *Daubert* motions seek to exclude FDA testimony and other regulatory or industry standards testimony. To the extent this Motion raises these issues it is **GRANTED in part** and **RESERVED in part** as described below.

I have repeatedly excluded evidence regarding the FDA's section 510(k)

clearance process in these MDLs, and will continue to do so in these case, a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913, 921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible prejudicial impact under Rule 403). Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See In re C. R. Bard,* 81 F.3d at 920 ("[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value."). Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors "to erroneously conclude that regulatory compliance proved safety." *Id.* at 922. Accordingly, expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, is **EXCLUDED**. For the same reasons, opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations are **EXCLUDED**. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue in these cases and runs the risk of misleading the jury and confusing the issues. Insofar as this Motion challenges the FDA-related testimony discussed here, the Motion is **GRANTED**.

A number of experts also seek to opine on Ethicon's compliance with design control and risk management standards. Some of this testimony involves the FDA's

quality systems regulations, and some—likely in an attempt to sidestep my anticipated prohibition on FDA testimony—involve foreign regulations and international standards. I find all of this proposed testimony of dubious relevance. Although these standards relate to how a manufacturer should structure and document risk assessment, the standards do not appear to mandate any particular design feature or prescribe the actual balance that must be struck in weighing a product's risk and utility. Nor is it clear that the European and other international standards discussed had any bearing on the U.S. medical device industry when the device in question was being designed.

Nevertheless, because the nuances of products liability law vary by state, I will refrain from issuing a blanket exclusion on design process and control standards testimony, whether rooted in the FDA or otherwise. Each standard must be assessed for its applicability to the safety questions at issue in this litigation, consistent with state law. I am without sufficient information to make these findings at this time. Accordingly, I **RESERVE** ruling on such matters until a hearing, where the trial judge will have additional context to carefully evaluate the relevance and potential prejudicial impact of specific testimony.

Similarly, I doubt the relevance of testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by the above discussion. Again, such matters seem to say very little about the state of the product itself (i.e., whether or not it was defective) when it went on the market. But because the scope

of relevant testimony may vary according to differences in state products liability law, I **RESERVE** ruling on such matters until they may be evaluated in proper context at hearing before the trial court before or at trial.

Additional—and more broad—matters also warrant mention. While some of these concerns may not apply to this particular expert, these concerns are raised so frequently that they are worth discussing here

First, many of the motions seek to exclude state-of-mind and legal-conclusion expert testimony. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury's fact-finding function by allowing testimony of this type, and I do the same here. *E.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g.*, *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) ("Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony."). Additionally, an expert may not offer expert testimony using "legal terms of art," such as "defective," "unreasonably dangerous," or "proximate cause." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

Second, and on a related note, many of the motions seek to prohibit an expert from parroting facts found in corporate documents and the like. I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose

of explaining the basis for his or her expert opinions—assuming the expert opinions are otherwise admissible—he or she may not offer testimony that is solely a conduit for corporate information.

Third, many of the motions also ask the court to require an expert to offer testimony consistent with that expert's deposition or report or the like. The court will not force an expert to testify one way or another. To the extent an expert offers inconsistent testimony, the matter is more appropriately handled via cross-examination or impeachment as appropriate and as provided by the Federal Rules of Evidence.

Fourth, in these *Daubert* motions, the parties have addressed tertiary evidentiary matters like whether certain statements should be excluded as hearsay. The court will not exclude an expert simply because a statement he or she discussed may constitute hearsay. *Cf. Daubert*, 509 U.S. at 595. Hearsay objections are more appropriately raised at trial.

Finally, in some of the *Daubert* motions, without identifying the specific expert testimony to be excluded, the parties ask the court to prevent experts from offering other expert testimony that the moving party claims the expert is not qualified to offer. I decline to make speculative or advisory rulings. I decline to exclude testimony where the party seeking exclusion does not provide specific content or context.

VI. Conclusion

The court **DENIES in part**, **GRANTS in part**, and **RESERVES in part** the Motion to Exclude the Opinions and Testimony of Shelby Thames [ECF No. 2039].

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 1 cases identified in the Exhibit attached hereto.

ENTER: September 2, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

Exhibit A - Thames Case Identification

Case No.	Case Style
2:11-cv-00809	Wilma Johnson v. Ethicon, et al.
2:12-cv-00256	Amy and Brent Holland v. Ethicon, et al.
2:12-cv-00258	Carrie Smith v. Ethicon, et al.
2:12-cv-00261	Mary F. Cone v. Ethicon, et al.
~~2:12-cv-00265~~	~~Doris Chappell Jackson v. Ethicon, et al.~~ WAVE 2
2:12-cv-00276	Cathy and John Warlick v. Ethicon, et al.
2:12-cv-00277	Joy and Kevin Essman v. Ethicon, et al.
2:12-cv-00279	Susan Thaman v. Ethicon, et al.
2:12-cv-00286	Quillan R. and Thomas W. Garnett v. Ethicon, et al.
2:12-cv-00322	Linda B. Ryan v. Ethicon, et al.
2:12-cv-00335	Sandra Wolfe v. Ethicon, et al.
2:12-cv-00337	Kathleen Wolfe v. Ethicon, et al.
2:12-cv-00341	Helen M. Brown and Robert E. Ruttkay v. Ethicon, et al.
2:12-cv-00344	Rose and Jesus Gomez v. Ethicon, et al.
2:12-cv-00347	Deborah and Felipe Lozano v. Ethicon, et al.
2:12-cv-00351	Kathy Barton v. Ethicon, et al.
~~2:12-cv-00352~~	~~Charlotte Hargrove v. Ethicon, et al.~~ CLOSED
2:12-cv-00358	Amanda and Raymond Deleon v. Ethicon, et al.
2:12-cv-00368	Sharon and Michael Boggs v. Ethicon, et al.
2:12-cv-00369	Dawna Hankins v. Ethicon, et al.
2:12-cv-00376	Charlene Logan Taylor v. Ethicon, et al.
~~2:12-cv-00378~~	~~Tina and Kenneth Morrow v. Ethicon, et al.~~ WAVE 2
2:12-cv-00379	Teri Key and Johnny Shively v. Ethicon, et al.
2:12-cv-00380	Terrie S. and Ralph R. Gregory v. Ethicon, et al.
~~2:12-cv-00381~~	~~Susan C. and Leonard Hayes v. Ethicon, et al.~~ CLOSED
2:12-cv-00387	Maru LuEllen and Thomas Lawrence Kilday v. Ethicon, et al.
2:12-cv-00389	Janice Renee Swaney v. Ethicon, et al.
~~2:12-cv-00397~~	~~Deborah A. Smith v. Ethicon, et al.~~ CLOSED
2:12-cv-00401	Carol Jean Dimock v. Ethicon, et al.
2:12-cv-00423	Pamela Free v. Ethicon, et al.
2:12-cv-00443	Holy and Jason Jones v. Ethicon, et al.
2:12-cv-00455	Pamela Gray-Wheeler and Stan Wheeler v. Ethicon, et al.
2:12-cv-00468	Amelia R. and Ernest B. Gonzales v. Ethicon, et al.
2:12-cv-00469	Patricia Tyler v. Ethicon, et al.
2:12-cv-00470	Mary Jane and Daniel Olson v. Ethicon, et al.
2:12-cv-00476	Harriet Beach v. Ethicon, et al.
2:12-cv-00481	Miranda Patterson v. Ethicon, et al.
2:12-cv-00483	Carey Beth and David Cole v. Ethicon, et al.
2:12-cv-00485	Danni Laffoon v. Ethicon, et al.
2:12-cv-00486	Karen and Joel Forester v. Ethicon, et al.
2:12-cv-00489	Melissa and Charles Clayton v. Ethicon, et al.
2:12-cv-00490	Shirley and William Freeman v. Ethicon, et al.
2:12-cv-00491	Gwendolyn T. Young v. Ethicon, et al.
2:12-cv-00493	Nancy and Daniel Hooper v. Ethicon, et al.

Case No.	Case Style
2:12-cv-00494	Penelope Ann Link and Dan Richard Saurino v. Ethicon, et al.
2:12-cv-00495	Andrea Carol and Mark Thomas Chandlee v. Ethicon, et al.
2:12-cv-00496	Sonya M. and James R. Moreland v. Ethicon, et al.
2:12-cv-00497	Dina Sanders Bennett v. Ethicon, et al.
2:12-cv-00498	Myndal Johnson v. Ethicon, et al.
2:12-cv-00499	Kimberly Thomas v. Ethicon, et al.
2:12-cv-00500	Krystal and Gregory Teasley v. Ethicon, et al.
2:12-cv-00501	Jennifer and David Sikes v. Ethicon, et al.
~~2:12-cv-00504~~	~~Donna T. and James W. Pilgreen v. Ethicon, et al.~~ CLOSED
2:12-cv-00505	Mary and Kenneth Thurston v. Ethicon, et al.
~~2:12-cv-00506~~	~~Martha and Stuart Newman v. Ethicon, et al.~~ CLOSED
2:12-cv-00510	Charlene Miracle v. Ethicon, et al.
2:12-cv-00511	Nancy Williams v. Ethicon, et al.
2:12-cv-00516	Patricia Conti v. Ethicon, et al.
2:12-cv-00517	Joann Lehman v. Ethicon, et al.
2:12-cv-00539	Ann Louise Ruppel and Robert Dean Fuller v. Ethicon, et al.
2:12-cv-00540	Nancy and Kenneth Feidler v. Ethicon, et al.
2:12-cv-00547	Brenda and James Riddell v. Ethicon, et al.
2:12-cv-00548	Rhoda Schachtman v. Ethicon, et al.
2:12-cv-00554	Sharon and Gardner Carpenter v. Ethicon, et al.
2:12-cv-00555	Carolyn Sue Doyle v. Ethicon, et al.
2:12-cv-00567	Noemi and Cesar Padilla v. Ethicon, et al.
2:12-cv-00571	Mary Catherine Wise v. Ethicon, et al.
2:12-cv-00591	Beverly Kivel v. Ethicon, et al.
2:12-cv-00594	Frances Ann and Herman Cortez v. Ethicon, et al.
2:12-cv-00595	Mary and Thomas Hendrix v. Ethicon, et al.
2:12-cv-00601	Deanna Jean and Bennie G. Thomas v. Ethicon, et al.
2:12-cv-00609	Patricia O. Powell v. Ethicon, et al.
2:12-cv-00651	Robin Bridges v. Ethicon, et al.
2:12-cv-00652	Maria C. and Mark A. Stone v. Ethicon, et al.
2:12-cv-00654	Stacy and Kevin Shultis v. Ethicon, et al.
2:12-cv-00657	Judy G. Williams v. Ethicon, et al.
2:12-cv-00663	Ana Ruebel v. Ethicon, et al.
2:12-cv-00666	Donna and Leon Loustaunau v. Ethicon, et al.
~~2:12-cv-00669~~	~~Teresa and Ricky J. Stout v. Ethicon, et al.~~ CLOSED
~~2:12-cv-00679~~	~~Lisa and Henry Stevens v. Ethicon, et al.~~ CLOSED
2:12-cv-00683	Louise Grabowski v. Ethicon, et al.
2:12-cv-00736	Karen and Thomas Daniell v. Ethicon, et al.
2:12-cv-00737	Beth and Stuart Harter v. Ethicon, et al.
2:12-cv-00738	Sheri and Gary Scholl v. Ethicon, et al.
2:12-cv-00746	Margaret Kirkpatrick v. Ethicon, et al.
2:12-cv-00747	Karyn E. and Douglas E. Drake v. Ethicon, et al.
2:12-cv-00748	Myra abd Richard Byrd v. Ethicon, et al.
2:12-cv-00749	Jennifer D. and Willem C.J. Van Rensburg v. Ethicon, et al.

Case No.	Case Style
2:12-cv-00751	Raquel and Ernesto De La Torre v. Ethicon, et al.
2:12-cv-00755	Cheryl Lankston v. Ethicon, et al.
2:12-cv-00756	Dee and Michael Woolsey v. Ethicon, et al.
2:12-cv-00757	Barbara Jean and Keith Bridges v. Ethicon, et al.
2:12-cv-00759	Diane and Robert Matott v. Ethicon, et al.
2:12-cv-00760	Lois and Gerald Durham v. Ethicon, et al.
2:12-cv-00761	Barbara J. and Gary L. Ware v. Ethicon, et al.
2:12-cv-00762	Janet D. Jones v. Ethicon, et al.
2:12-cv-00765	Rachel and Dwan Taylor v. Ethicon, et al.
~~2:12-cv-00766~~	~~Kimberly Garnto v. Ethicon, et al.~~ CLOSED
~~2:12-cv-00767~~	~~Rebecca and Charles Oehring v. Ethicon, et al.~~ CLOSED
~~2:12-cv-00768~~	~~Sandra and Christian LaBadie v. Ethicon, et al.~~ CLOSED
2:12-cv-00769	Kimberly T. Burnham v. Ethicon, et al.
2:12-cv-00772	Harmony Minniefield v. Ethicon, et al.
2:12-cv-00773	Tina and Keith Patterson v. Ethicon, et al.
2:12-cv-00779	Dee and Timothy McBrayer v. Ethicon, et al.
2:12-cv-00783	Wendy Hagans v. Ethicon, et al.
~~2:12-cv-00784~~	~~Schultz et al v. Ethicon, Inc. et al~~ CLOSED
2:12-cv-00786	Swint et al v. Ethicon, Inc et al
2:12-cv-00787	Joplin v. Ethicon, Inc et al
2:12-cv-00799	Quijano v. Ethicon, Inc. et al
2:12-cv-00800	Morrison et al v. Ethicon, Inc et al
2:12-cv-00806	Hill et al v. Ethicon, Inc. et al
2:12-cv-00807	Sweeney et al v. Ethicon, Inc. et al
2:12-cv-00811	Zoltowski et al v. Johnson & Johnson et al
2:12-cv-00821	Barr et al v. Ethicon, Inc. et al
~~2:12-cv-00828~~	~~Nix et al v. Ethicon, Inc. et al~~ CLOSED
2:12-cv-00829	Georgilakis et al v. Ethicon, Inc et at
~~2:12-cv-00830~~	~~Parrilla v. Ethicon, Inc. et al~~ CLOSED
2:12-cv-00842	Stubblefield v. Ethicon, Inc. et al
2:12-cv-00846	Raines et al v. Ethicon, Inc. et al
2:12-cv-00848	Fisk v. Ethicon, Inc et al
2:12-cv-00854	Ballard et al v. Ethicon, Inc et al
2:12-cv-00856	Massicot v. Ethicon, Inc. et al
~~2:12-cv-00859~~	~~Olmstead v. Ethicon, Inc. et al~~ CLOSED
2:12-cv-00860	Pelton v. Ethicon, Inc. et al
~~2:12-cv-00861~~	~~Smith et al v. Ethicon, Inc. et al~~ CLOSED
2:12-cv-00863	Gunter et al v. Ethicon, Inc
2:12-cv-00864	Nolan v. Ethicon, Inc. et al
2:12-cv-00867	Rock v. Ethicon et al
2:12-cv-00873	Walker et al v. Ethicon, Inc. et al
2:12-cv-00875	Holzerland et al v. Ethicon, Inc. et al
2:12-cv-00876	Hoy et al v. Ethicon, Inc. et al
2:12-cv-00878	Fox et al v. Johnson & Johnson, Inc. et al

Case No.	Case Style
2:12-cv-00880	Massey et al v. Ethicon, Inc. et al
2:12-cv-00883	Wroble et al v. Ethicon, Inc et al
~~2:12-cv-00886~~	~~Umberger et al v. Ethicon, Inc. et al~~ CLOSED
2:12-cv-00887	Kaiser et al v. Johnson & Johnson et al
2:12-cv-00888	Bruhn et al v. Ethicon, Inc et al
2:12-cv-00899	Barker et al v. Ethicon, Inc. et al
~~2:12-cv-00921~~	~~Wilson v. Ethicon, Inc et al~~ CLOSED
~~2:12-cv-00923~~	~~Atemnkeng et al v. Ethicon, Inc. et al~~ CLOSED
2:12-cv-00931	Collins v. Ethicon, Inc. et al
2:12-cv-00938	Kriz et al v. Ethicon, Inc. et al
2:12-cv-00939	Reyes et al v. Ethicon, Inc. et al
2:12-cv-00956	Justus v. Ethicon, Inc. et al
2:12-cv-00957	Funderburke v. Ethicon, Inc. et al
2:12-cv-00958	White et al v. Ethicon, Inc. et al
2:12-cv-00960	Amsden et al v. Ethicon, Inc. et al
2:12-cv-00961	Greene v. Ethicon, Inc. et al
2:12-cv-00967	Shepherd v. Ethicon, Inc. et al
2:12-cv-00995	Blake et al v. Ethicon, Inc. et al
2:12-cv-00997	Springer et al v. Ethicon, Inc. et al
2:12-cv-01004	Frye v. Ethicon, Inc. et al
2:12-cv-01011	Hankins et al v. Ethicon, Inc. et al
2:12-cv-01013	Lee et al v. Ethicon, Inc. et al
~~2:12-cv-01018~~	~~Gwinn et al v. Ethicon, Inc. et al~~ CLOSED
2:12-cv-01021	Ruiz v. Ethicon, Inc. et al
2:12-cv-01023	Burkhart v. Ethicon, Inc. et al
2:12-cv-01052	Babcock v. Ethicon, Inc. et al
2:12-cv-01053	Baugher v. Ethicon, Inc. et al
2:12-cv-01071	Schnering et al v. Ethicon, Inc. et al
2:12-cv-01081	Dixon v. Ethicon, Inc. et al
2:12-cv-01088	Wheeler et al v. Ethicon, Inc. et al
2:12-cv-01090	Wright v. Ethicon, Inc. et al
2:12-cv-01119	Rhynehart v. Ethicon, Inc. et al
2:12-cv-01121	Guinn v. Ethicon, Inc. et al
2:12-cv-01124	Bellito-Stanford et al v. Ethicon, Inc. et al
2:12-cv-01145	Constance Daino v. Ethicon, Inc. et al
2:12-cv-01146	Monica Freitas v. Ethicon, Inc. et al
2:12-cv-01148	Denise Sacchetti v. Ethicon, Inc. et al
2:12-cv-01149	Cindy Smith v. Ethicon, Inc. et al
2:12-cv-01150	Roberta Warmack v. Ethicon, Inc. et al
2:12-cv-01151	Laura Waynick v. Ethicon, Inc. et al
2:12-cv-01171	Patti Ann Phelps v. Ethicon, Inc. et al
2:12-cv-01198	Stacy Pangborn v. Ethicon, Inc. et al
2:12-cv-01199	Lisa Thompson v. Ethicon, Inc. et al
2:12-cv-01202	Diane Kropf v. Ethicon, Inc. et al

Case No.	Case Style
2:12-cv-01203	Joan Adams v. Ethicon, Inc. et al
2:12-cv-01206	Jeanie Holmes v. Ethicon, Inc. et al
2:12-cv-01215	Karen Bollinger v. Ethicon, Inc. et al
2:12-cv-01216	Christine Wiltgen v. Ethicon, Inc. et al
2:12-cv-01225	Ida Deanne Evans v. Ethicon, Inc. et al
~~2:12-cv-01262~~	~~Saundra Landes v. Ethicon, Inc. et al~~ CLOSED
2:12-cv-01267	Angela Coleman v. Ethicon, Inc. et al
2:12-cv-01273	Rebekah Barlett v. Ethicon, Inc. et al
2:12-cv-01274	Janice Colonna v. Ethicon, Inc. et al
2:12-cv-01275	Long v. Johnson & Johnson et al
2:12-cv-01277	Duncan v. Ethicon, Inc et al
2:12-cv-01278	Nix v. Ethicon, Inc. et al
2:12-cv-01279	Bertoni et al v. Ethicon, Inc. et al
2:12-cv-01283	Cyrus v. Ethicon, Inc. et al
2:12-cv-01284	~~Floyd~~ v. Ethicon, Inc. et al Judith Gowin
2:12-cv-01285	Simpson et al v. Ethicon, Inc. et al
2:12-cv-01286	Wilson v. Ethicon, Inc. et al
2:12-cv-01293	Costello v. Ethicon, Inc. et al
~~2:12-cv-01294~~	~~Herrera-Nevarez v. Ethicon, Inc~~ CLOSED
2:12-cv-01299	Destefano-Rasten et al v. Ethicon, Inc. et al
2:12-cv-01304	Irwin et al v. Ethicon, Inc. et al
2:12-cv-01305	Lager v. Ethicon, Inc. et al
2:12-cv-01311	Ridgley et al v. Ethicon, Inc. et al
2:12-cv-01318	~~Banks~~ v. Johnson & Johnson, Inc. et al Marie Smith